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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,108	04/06/2000	Kenneth Eliot Sherman		7634

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/544,108	SHERMAN, KENNETH ELIOT	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 5, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed October 5, 2007 in response to the Office Action of May 31, 2007 is acknowledged and has been entered. Claims 1, 3-6, and 25 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of claims 1, 3-6, and 25 under 35 U.S.C. 103(a) as being unpatentable over Huang (Virologica Sinica, 1990, Vol. 5, p. 69-73) in view of Hoofnagle et al. (of record in IDS of May 6, 2002) and Moody et al. (US Patent 5,273,963) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicant argues that Applicant has found that improved results are achieved with a combination therapy over using either α-interferon or thymosin α. alone. In response to Applicant's arguments it is the Office's position that the unexpected results argued by the Applicant do not have support in the present specification. The specification does not provide working examples that support the above statement with regard to the improved results using combination therapy over using either α-interferon or thymosin α. alone. There is lack of figures or drawings that could provide evidence of the unexpected results argued by the applicant. The examples in the specification generally discuss a proposed clinical study, in which α-interferon together with thymosin α. could be administered to HCV infected patients. From the examples of the specification it does

not appear that the proposed clinical study has been conducted. The examples do not provide any mention of the outcome of the study, and there is lack of scientific data that could support Applicants arguments. Therefore Applicant's arguments with regard to the unexpected results are not found persuasive.

Applicant further argues that the cited references whether alone or in combination do not suggest the present method. The Examiner respectfully disagrees with Applicant's contention. As discussed in the rejection of record, the method of administering α-interferon to treat hepatitis C infection has been known in the art at the time of the present invention, as evidenced by Hoofnagle. The methods of using α.-interferon in combination with thymosin α to treat hepatitis B have been known in the art at the time of the present invention, as evidenced by Huang. Although, the combination of α.-interferon with thymosin α has been used to treat HBV and not HCV, as required by the present claims, the immunopotentiating effects of α.-interferon in combination with thymosin α have been known to the artisan at the time of the present invention. Although, the HCV and HBV are distinct viruses, and their pathologies are not exactly the same, as argued by the Applicant, the immunological mechanism of action of thymosin α that is the stimulation of production of α.-interferon, the purpose of administration of thymosin α., and the expected outcomes in both cases (HCV and HBV infection) are the same. Thus because it has been known in the art that thymosin α acts to stimulate and enhance the action of α-interferon, one would have been motivated to add Huang's and Moody's thymosin α to Hoofnagle's composition comprising α-interferon and to use the combination of α-interferon and thymosin α to treat HCV infection.

Absent unexpected results, and in view of the art of record, it is the Office's position that the present method would have been obvious to the artisan at the time of the present invention.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 12-26-2007
Primary Examiner, TC1600